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IS 13809 (Part 1) : 1993
(Reaffirmed 2003)

भारतीय मानक

निदान एवं रक्त संचरण सेवाओं के लिए गुणता प्रबन्ध प्रक्रिया – मार्गदर्शी सिद्धान्त

भाग 1 30-संसतरित अस्पताल तक

Indian Standard

QUALITY MANAGEMENT PROCEDURES FOR DIAGNOSTIC AND BLOOD TRANSFUSION SERVICES — GUIDELINES

PART 1 UP TO 30-BEDDED HOSPITALS

UDC 362·111 : 615·38

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BUREAU OF INDIAN STANDARDS
MANAK BHAVAN 9 BAHADUR SHAH ZAFAR MARG
NEW DELHI 110002

July 1993 **Price Group 5**

FOREWORD

This Indian Standard (Part 1) was adopted by the Bureau of Indian Standards, after the draft finalized by the Hospital and Medical Care Services Sectional Committee had been approved by the Management and Systems Division Council.

There is a felt need for quality management and quality assurance procedures in hospital services so as to make the same more effective, economical and accountable. Once a health and medical care facility has been planned and provided with required instruments and equipment, there is a need to manage the facility scientifically so that quality service is provided to patients on a continued basis. While basic management principles and individual skills are helpful in such efforts, optimum results can be achieved only if certain standards and guidelines are available for the management and operational systems of health and medical care services. For this purpose, it would be necessary, as a first step, to lay down norms and standards and then to provide the requisite infrastructure needed for achieving the desired targets.

Most of the 30-bedded hospitals in the country, particularly in rural areas, lack in the basic facilities leading to dissatisfaction to user community. Therefore, there is an imperative need to set up some guidelines and standards for upgradation (both qualitative as well as quantitative) of diagnostic facilities along with the requisite infrastructure in the existing 30-bedded hospitals and also for starting the new ones.

Quality assurance activity of Diagnostic Services Department aims at providing the most accurate, precise and timely test results and preventing the occurrence of errors. This activity is not confined to one or two individuals, but is the responsibility of everyone in the department.

A good quality assurance programme for a Diagnostic Services Department has three major aspects – Preventive activities; Assessment procedures; and Corrective actions. Preventive activities are taken to avoid errors and ensure accuracy and precision. Method selection, careful laboratory design, hiring of competent personnel, development of comprehensive procedure manuals and effective preventive maintenance programmes are a few examples of preventive activities. Assessment procedures monitor the analytical process to determine the type and amount of error and the change in accuracy and precision in the process. These activities include the testing of quality control material, performing instrument function checks, and participating in proficiency testing programmes. Corrective actions are taken to rectify errors after discovery and include useful and timely communication with the users of the laboratory's services, review of work, and of instrument problems.

Blood is a biological product of human beings, the correct administration of which is a life saving measure in many critical conditions. No general hospital can hope to fulfill all its responsibilities and obligations until and unless it has access to safe blood transfusion facilities. The recent trend all over the world is to organize and manage blood transfusion service as an integral part of the diagnostic services specially in small general hospitals of this size.

30-bedded hospitals are quite small in size and infrastructure where it is not feasible to create the entire set up of a Blood Bank because of the economics of demand and supply. Hence, it is proposed to set up a Blood Transfusion Centre with basic facilities in place of blood bank, in a 30-bedded general hospital. In India, the setting up of a Blood Transfusion Centre shall be according to the criteria laid down by Drug and Cosmetic Act, 1948.

The committee responsible for the formulation of this standard is given at Annex D.

The purpose of this standard is to provide the basic guidelines for evolving a well-planned quality assurance programme which would result in quality health care to the patients in relation to diagnostic and blood transfusion services in a 30-bedded general hospital.

This standard is mainly for 30-bedded hospitals such as community health centres/sub-district hospitals/intermediate hospitals. Other standards in this series which will be published in due course are as follows:

Quality management procedures for:

OPD and emergency services—Guidelines

Wards, nursing services and operation theatre—Guidelines

Hospital support services—Guidelines

Hospital engineering services—Guidelines

Indian Standard

QUALITY MANAGEMENT PROCEDURES FOR DIAGNOSTIC AND BLOOD TRANSFUSION SERVICES — GUIDELINES

PART 1 UP TO 30-BEDDED HOSPITALS

1 SCOPE

This standard (Part 1) lays down guidelines for quality management procedures for diagnostic and blood transfusion services offered in 30-bedded general hospitals with reference to:

a) Pathological Services — The system of collection of blood, urine, and other body fluid samples and their processing.

b) Imaging Services — The system of imaging of patients by X-ray and Ultrasound.

c) ECG Services

d) Blood Transfusion Services.

2 REFERENCE

The following Indian Standard is a necessary adjunct to this standard:

IS No.	*Title*
12433 (Part 1) : 1988	Basic requirements for hospital planning : Part 1 Up to 30-bedded hospitals

3 TERMINOLOGY

For the purpose of this standard, the following definitions shall apply.

3.1 Blood Transfusion Services

Facility responsible for safe and effective collection, storage, processing and distribution of blood.

3.2 Diagnostic Services

The procedure involving the use of technology by medical or paramedical personnel to know the nature, extent and the cause of disease.

3.3 Laboratory

Place of investigations.

3.3.1 *Biochemistry*

Study of chemical or physio-chemical processes and values of normal and abnormal products of metabolism of carbohydrates, fats, proteins, etc.

3.3.2 *Haematology*

Qualitative and quantitative study of blood and blood components.

3.3.3 *Pathology*

The science of analysis of diseased tissue or fluids and other elements in the body.

3.3.4 *Serology*

Science of study of factors present in serum. These factors may include antibodies to bacteria, virus and other antigens and blood grouping systems.

3.3.5 *Microbiology*

Study of micro-organisms.

3.4 Radiology

The science of imaging by X-ray.

3.5 Ultrasonography

Science of imaging by the use of ultrasound waves.

3.6 Electro Cardio Graph (ECG)

Study of electro-physiological changes in the heart.

3.7 Restricted Emergency Services

Emergency services which are rendered as and when required by placing staff on call.

3.8 Medical Audit

A systematic and critical evaluation of the quality of medical care in retrospect, through analysis of clinical records.

NOTES

1 Clinical records include procedures used for diagnosis and treatment, the use of resources and the resulting outcome and quality of life for the patient.

2 The purpose of medical audit is to identify opportunities and to implement improvement in:

- — quality of medical care,
- — medical training and continuing education,
- — efficient and effective use of resources, and
- — assessment of patient satisfaction.

4 PLANNING

4.1 Physical Facilities

4.1.1 *Location*

There should be a separate wing for Diagnostic Services Department attached to the main hospital site such that, it is:

a) easily accessible to both indoor and outdoor patients,

b) easily accessible to the operation theatre department,

c) preferably on the ground floor.

Blood transfusion centre should be adjacent to the diagnostic services department since many of the functions will be common.

4.1.2 *Functional and Space Requirements*

For functional and space requirements of diagnostic zone, reference shall be made to 7 of IS 12433 (Part 1) : 1988.

Functional and space requirements for blood transfusion services may be as recommended in Annex A.

4.2 Expected Workload

4.2.1 The expected number of laboratory/radiographic investigations may depend on number of factors. However, a rough criteria is that,

> a minimum of 1/3 of the OPD patients and 2/3 of the inpatients with 2 to 3 investigations per patient require laboratory investigations per day
>
> a minimum of 1/6 of the OPD patients and 1/3 of the inpatients with atleast one investigation per patient require radiological investigations per day

Depending upon the number of inpatients and the expected number of outpatients in a day, which is estimated as 150-180 outpatients per day for a 30-bedded hospital, the expected number of laboratory investigation is estimated as 170-180 investigations per day and that of radiological investigations is estimated as 35-40 investigations per day.

4.2.2 The workload of the blood transfusion services varies according to the type, size, utilization and functional activities of hospital. However, for a 30-bedded hospital an estimate according to WHO may be as given below:

(Number of beds - 30%) × 7
= 30 - (30% of 30) × 7
= (30 - 9) × 7
= 21 × 7 = 147
= 150 unit per year

4.3 Staff, Instruments and Equipment Requirements

4.3.1 For manpower requirements of the diagnostic services, reference may be made to **8** of IS 12433 (Part 1) : 1988.

4.3.2 For instruments and equipment requirements of the diagnostic services, reference may be made to **9** of IS 12433 (Part 1) : 1988.

4.3.3 Staff, instruments and equipment requirements for blood transfusion services may be as recommended in Annex A.

5 ORGANIZATION STRUCTURE

With a view to provide an efficient quality management system there should be a well organized structure for Diagnostic and Blood Transfusion Services. The flow of activities under the diagnostic (pathological, imaging and ECG) and blood transfusion services have been indicated in the diagram given in Annex B.

The various activities under each of these services will be carried out by the respective medical/paramedical personnel. The overall functioning of these services should be under the control of a designated medical officer-in-charge who would be overseeing the day-to-day functioning of these services in addition to his other duties.

6 FUNCTIONAL MANAGEMENT

6.1 Timings of Diagnostic and Blood Transfusion Services

6.1.1 It is recommended that Diagnostic Services Department may work for 7 hours per day (0 900 h-1 600 h) for 6 days in a week. Collection of the laboratory samples for pathological investigations may be done for 3 hours in the morning (0 900 h-1 200 h) and requisition for X-rays/ultrasound/ECG may be accepted for 4 hours in the morning (0 900 h-1 300 h).

The department shall run on restricted emergency basis also.

6.1.2 The blood transfusion centre shall run for 7 hours per day (0 900 h-1 600 h) and it shall run on restricted emergency basis also.

6.2 Functional Activities under Diagnostic Services

There is a need to enhance the scope of Diagnostic Services Department so that the number of patients requiring admission can be minimized. Effective and efficient functioning of the department will facilitate this objective. To achieve this objective, it will be necessary that a detailed diagnosis at the clinical laboratory and imaging section should be undertaken and the patients requiring admission alone may be admitted to the hospital.

The main functions of the diagnostic services department are to provide facilities for investigations (pathological, radiological and ECG) for all kinds of patient care services including restricted emergency services. The doctors from the Out Patient Department (OPD) or Wards (IPD) would fill up the requisition form for the investigation(s) required, which may be as given in Annex C, common to all types of investigations. Separate requisition forms should be filled for different type of investigations.

A typical flow diagram for various functional activities in Diagnostic Services Department may be as given in Annex B.

6.2.1 *Pathological Services*

6.2.1.1 *Reception and Registration*

A system for registration of patients should exist for:

a) Identification of samples,

b) Recording of type and number of investigations,

c) Recording of personal data for identification.

The particulars of the patient and investigations required should be registered in the laboratory according to the following proforma:

Date	Sl No.	Name	IPD/OPD No.	No. and Nature of Tests	Remarks

This Serial Number should also be entered both in the OPD card as well as the requisition slip.

6.2.1.2 *Collection of samples*

The blood, urine and other fluid samples should be collected for processing which may involve:

a) Receiving urine, stool, etc, other than blood samples;

b) Withdrawal of intravenous/capillary blood in specified vials/containers using a disposable syringe or atleast a disposable needle for each patient;

c) Labelling and numbering of samples; and

d) Matching the serial number of registration.

The samples collected should be labelled with the patient's name, registration number, date and time of collection (if relevant) and the serial number. Alternatively, a codification system, as the one recommended below may be followed for labelling the samples received in the laboratory:

'Laboratory code Sl No./Date'

for example L 1/2609
L 2/2609
L 3/2609

6.2.1.3 *Processing and reporting*

A laboratory should be provided for biochemistry; clinical pathology and haematology; serology; and microbiology. The functioning of the laboratory will include:

a) Processing of collected samples,

b) Entry of test report in laboratory registers,

c) Reporting of results in the requisition form itself with the proper stamping of the test carried out with their normal values.

The samples collected shall be processed and test results entered in the respective register for reporting of test results (for example, Report Register for blood, urine, etc, in the required format). The test results shall also be entered in the requisition form.

6.2.1.4 *Despatch of Reports*

This involves:

a) Arrangement for classifying reports of respective OPD/Wards,

b) Entry in despatch registers,

c) Distribution of reports in person/through messengers.

The requisition form including the test report shall be sent to the OPD registration counter for the outpatients and to the wards for the inpatients after making appropriate entry in the 'Remarks' column of the register in **6.2.1.1**.

6.2.2 *Imaging Services*

This unit deals with radio-diagnosis and ultrasound.

6.2.2.1 *Reception and Registration*

A system for registration of patients should exist for:

a) registration of patients for X-rays/ultrasound;

b) assignment of registration number; and

c) imparting of special instruction, if any, in printed form.

6.2.2.2 *Preparation of patients for imaging*

A separate radiography room may be provided for imaging by X-ray and ultrasound and a change room may also be provided separately or along with the radiography room.

6.2.2.3 *Processing and inferring*

Film developing and dark room shall be provided in the department for loading, unloading, developing and processing of X-ray films. The room shall be completely cut-off from direct light through provision of light barrier. For ventilations, exhaust fans shall be provided.

The exposed X-ray films and ultrasound outputs shall be used for drawing inferences and recording ther as reports in the requisition form itself.

6.2.2.4 *Documentation and despatch*

The X-ray and ultrasound reports shall also be documented in the registers maintained in the radiography room before despatch.

The records of developed X-ray films and ultrasound outputs shall be maintained in a separate record room with proper identification system which may be needed at subsequent visits of the patients.

6.2.3 *ECG Services*

6.2.3.1 *Reception and registration*

A system for registration of patients should exist for

a) registration of patients for ECG

b) assignment of registration number

6.2.3.2 *Recording of ECG*

A separate room should be provided for recording of ECG of the patient.

6.2.3.3 *Despatch of reports*

The particulars of the patient as given in the requisition form should be recorded in the despatch register maintained in the ECG room before handing over the ECG tracing to the patient or his representative. The report of ECG may also be recorded in the despatch register.

6.3 Functional Activities Under Blood Transfusion Services

Blood transfusion service should ensure safe transfusion of blood through appropriate process of collection, storage, cross-matching and screening of donors' blood including the laboratory tests for Hepatitis B (HBS Ag), HIV (AIDS), Malaria and VDRL. Blood should be accepted from donors on strictly non-remunerative and voluntary basis and also from relatives/friends donors. On no account should blood be accepted from professional blood sellers.

The source of blood should generally be regional blood bank. However, for emergency use, a list of voluntary donors whose blood has already been screened should be maintained instead of storing the blood in a 30-bedded hospital since the shelf life of blood is short and also the consumption not being very high in a small hospital. Stocks of blood substitutes, like plasma, etc, may be maintained instead. Liaison may be maintained with other bigger hospitals/blood banks in the vicinity for situations when blood collected if not be used in time, may be transferred to these hospitals/blood banks with an understanding that as and when this hospital would need blood in an emergency, it could be given to them in lieu/on loan. Appropriate facilities for the trans-shipment of blood should also be made available.

Adequate provision should be made for clean, soft water; electricity; light and ventilation; snacks and tea/coffee for the donors.

7 PROCEDURE MANUAL

7.1 A standard manual should be developed and followed with regard to each area of diagnostic services including various investigations to be carried out and other day-to-day work of the department. This may include staff development, method of test, maintenance of equipment, storage of materials and disposal of diagnostic waste.

For blood transfusion services, **standard** technical procedures should be followed as laid down by the Government of India/State Governments.

7.1.1 *Personnel Development*

The staff (including technical staff) of diagnostic and blood transfusion services should be fully qualified, well trained and experienced in their respective activities. The staff of blood transfusion services should be specially trained in blood transfusion technology including HIV testing.

To keep an employee abreast of the current state of technology and to keep skills refreshed, there should be an active continuing education programme.

On the job checklist may be given to the technicians to guide them with regard to the various activities performed by them for monitoring their own performance.

7.1.2 *Method of Test*

Each test performed in the laboratory should have a separate procedure containing pertinent information written in a uniform style which may include special directions for patient preparation, directions for the preparation of reagents and other material required, complete instruction for performing the test procedures, reporting of test results, etc. The Standing Operating Procedures (SOP) for the same shall be prepared and followed for the respective diagnostic services.

7.1.3 *Maintenance of Equipment and Materials Management*

7.1.3.1 *Maintenance of equipment*

A separate history sheet should be maintained for each equipment giving details of name of equipment, date of purchase, cost of equipment, source or supplier, life of equipment, maintenance schedule (including calibration, if required), breakdowns, repairs and cost of repairs, etc. The equipment may be recommended for condemnation if it breaks down repeatedly incurring heavy expenditure and becomes beyond economical repair or obsolete model. Efforts should be made to keep a good liaison with larger hospitals and other technical people for maintenance of equipment as and when required.

7.1.3.2 *Storage and handling of materials*

Laid down procedures regarding procurement, storage and disposal of reagents; chemicals; X-ray paper and ECG paper; and kits; etc, should be strictly adhered to and records should be maintained indicating their consumption, expiry date, required level of inventory and present position of stock.

As regards to blood transfusion services, adequate buffer stores of consummables like antisera, and disposables may be kept keeping in view the possibilities of erratic supplies.

8 PERFORMANCE EVALUATION

A suitable mechanism should be available with requisite infrastructural facilities for evaluating the performance of diagnostic and blood transfusion services offered. For example, a fixed number of cases in a month at random shall have an audit by a Medical Audit Committee. Every functional area of Diagnostic and Blood Transfusion Services should be evaluated by this Committee to assess the efficacy of the system. The feedback arising out of such evaluation should be recorded and made use of in improving the quality related activities of diagnostic and blood transfusion services in future.

ANNEX A

(*Clauses* 4.1.2 *and* 4.3.3)

BASIC REQUIREMENTS FOR BLOOD TRANSFUSION SERVICES IN A 30-BEDDED GENERAL HOSPITAL

A-1 FUNCTIONAL AND SPACE REQUIREMENTS

One room of size 5m × 6.5m should be kept for blood transfusion services. This room may be divided into various cubicles for the following facilities:

Examination Records and Store Area	Mini Lab Storage of Blood and Staff Working Area
Bleeding Area	

A-2 STAFF, INSTRUMENTS AND EQUIPMENT REQUIREMENTS

A-2.1 Manpower Requirements

It is recommended that the staff of the diagnostic services department may be trained in the science of blood transfusion. However, in addition, the following staff may be required for blood transfusion services:

	Min
Technologist - Blood Transfusion/Haematology	1
Technical Aid	1 (to be shared with the paramedical staff of the hospital)

A-2.2 Instruments and Equipment Requirements

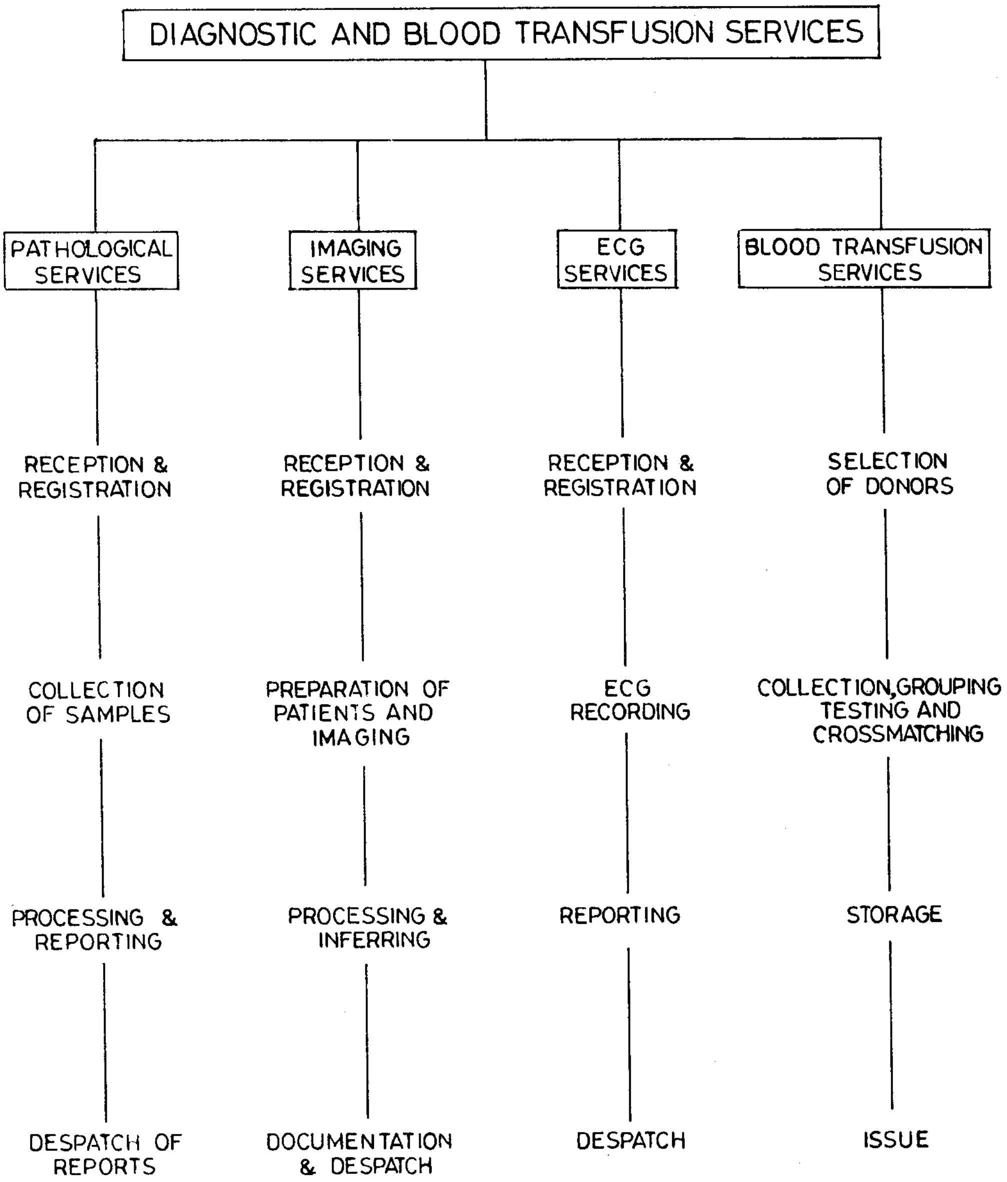
The following instruments and equipments are recommended for blood transfusion services:

	Min	
Blood Bank Refrigerator	1	Special Features: — Low temperature up to 0°C — Cabinet fan cooled — Temperature recording device — Power supply backup generator
Microscope	1	Binocular
Facility for screening the blood samples from HIV (AIDS) and HBS Ag (Elisa Reader).	1	
Elisa Reagents and kits		
Blood bags		
Water bath	1	
Pasteur pipettes		
Serology tubes racks		
Grease pencil and glass marking pens		
Microscope slides		

ANNEX B

(*Clauses* 5 *and* 6.2)

FLOW OF ACTIVITIES FOR DIAGNOSTIC AND BLOOD TRANSFUSION SERVICES



ANNEX C

(*Clause* 6.2)

REQUISITION SLIP

Name : .... OPD/IPD No. ....

Age : .... Sex : .... Date ....

Investigations Required : ....

Brief Clinical Notes :

Results :

ANNEX D

(Foreword)

COMMITTEE COMPOSITION

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Dr R. N. Baishya (*Alternate*)	
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Head of The Department of Anaesthesiology (*Alternate* 1)	
Head of The Department of Radiodiagnosis (*Alternate* 2)	
Dr P. N. Ghei	Indian Hospital Association, New Delhi
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Doc : No. MSD 8 (29)

Amendments Issued Since Publication

Amend No.	Date of Issue	Text Affected

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AMENDMENT NO. 1 NOVEMBER 1994
TO
IS 13809 (Part 1) : 1993 QUALITY MANAGEMENT PROCEDURES FOR DIAGNOSTIC AND BLOOD TRANSFUSION SERVICES — GUIDELINES

PART 1 UP TO 30-BEDDED HOSPITALS

(*First cover page and all other relevant pages, designation*) — Substitute 'IS 13808 (Part 2) : 1993' *for* 'IS 13809 (Part 1) : 1993'.

(*First cover page, page* 1, *title*) — Substitute the following for the existing title:

'QUALITY MANAGEMENT FOR HOSPITAL SERVICES (UP TO 30-BEDDED HOSPITALS) — GUIDELINES

PART 2 DIAGNOSTIC AND BLOOD TRANSFUSION SERVICES'

(*Second cover page, Foreword*) — Add the following para at the end:

'This series of standards for 30-bedded hospitals covers only a part of quality management aspect in hospital services and relates to infrastructure, skills, procedures and systems, etc, which is a prescription type provision, adherence to which is expected to result in service of desired quality. The second part, comprising of identification of attributes of quality and quantifying them, that is, performance type of standards for hospital services would be published in due course.'

(*Page* 2, *clause* **4.2.2**, *line* 7) — Substitute the following for the existing equality:

'$= [30 - (30\% \text{ of } 30)] \times 7$'.

(MSD 8)

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